## Remarks

Claims 40, 41, 48, 60 and 61 were pending. By this amendment, claim 40 is amended. Claims 62 -65 are new. Support for claim amendment 40 and newly added claims 62-65 can be found throughout the specification, including page 39, line 16 – page 41, line 28, Example 13 and Example 14. Claims 41, 48, 60 and 61 are canceled without prejudice. Applicants reserve the right to pursue canceled subject matter in continuing applications.

No new matter is introduced by the foregoing amendments. After entry of this amendment, claims 40 and 62-65 are pending in the application. Reconsideration of the pending claims is respectfully requested.

***Drawings***

Applicants have amended the specification to include a sequence identifier number (SEQ ID NO.) for each of the separate sequences referred to in Figure 3A. Applicants also submit herewith an amended sequence listing and statement in compliance. As such, Applicants believe that the specification is now in compliance with 37 C.F.R. § 1.81(d).

***Specification Objections***

The specification is objected to for allegedly disclosing sequences that are not identified by a SEQ ID NO. The specification has been reviewed and amended so that all nucleotide sequences with ten or more bases and all amino acid sequences with four or more amino acids are identified by a specific SEQ ID NO. Therefore, Applicants believe that the specification is now in compliance with 37 C.F.R. § 1.81(d).

***Claim Objections***

Claims 40, 41, 48, 60 and 61 are objected to for encompassing non-elected subject matter. The Office fails to state the objectionable non-elected subject matter in these claims. However, claim 40 has been amended and claims 41, 48, 60 and 61 have been canceled. Applicants believe that these amendments render the pending objections moot.

***Claim Rejections:***

*35 U.S.C. § 112, second paragraph*

Claims 40, 41, 48, 60 and 61 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. In particular, claim 40 is alleged to be indefinite for reciting the phrase "Rab11A enzymatic activity" and claim 48 for reciting "retrovirus comprises ...." Claim 40 has been amended. Claims 41, 48, 60 and 61 have been canceled. Applicants believe that the pending claims are definite and request that the pending 35 U.S.C. §112, second paragraph, rejection be withdrawn.

*35 U.S.C. § 112, first paragraph*

**(a) Enablement:**

Claims 40, 41, 48, 60 and 61 have been rejected under 35 U.S.C. §112, first paragraph as allegedly not being enabled by the specification. In particular, the Office contends that the specification does not reasonably provide enablement for any biochemical, cellular or *in vivo* method for identifying an agent that decreases pathogenicity of any retrovirus. Claims 41, 48, 60 and 61 have been canceled. Amended claim 40 is directed to a method of identifying an agent that decreases viral infection. Applicants believe these amendments render the pending 35 U.S.C. §112, first paragraph, rejection moot. Further, Applicants respectfully, but adamantly disagree with the pending enablement rejection as it may be applied to the amended claims for at least the following reasons.

As the Office is aware, "[t]he test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue" (citing *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976)). Here, although routine assays may be required in order to select optimal screening conditions of the claimed invention, no undue experimentation is required to practice the full scope of the invention. Applicants submit that the emphasis in this test is on "undue," and not on "experimentation" (see *In re Wands*, 858 F.2d 731, 736-40 (Fed. Cir. 1988)). As the Office is no doubt aware, the determination of what is meant by "undue experimentation" has been characterized by the Federal Circuit as follows (*Genentech, Inc.* v. *Novo Nordisk A/S*, 108 F.3d at 1365):

> [t]he test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention.

In the current case, any necessary experiment is merely routine, and thus not undue. The specification provides numerous exemplary methods for identifying agents that decrease viral infection by monitoring Rab11A activity or expression, including page 39, line 16 – page 41, line 28, Example 13 and Example 14. All of these methods are routine and known to those of ordinary skill in the art. Therefore, it is believed that any experiment is well within the limits set by the *Genentech* court. As such, Applicants believe that the claims as presented herein are fully enabled by the specification and satisfy the enablement requirement of 35 U.S.C. §112, first paragraph.

**(b) Written Description**

Claims 40, 41, 48, 60 and 61 have been rejected under 35 U.S.C. §112, first paragraph as allegedly failing to satisfy the written description requirement. In particular, the Office contends that the specification does not reasonably provide written description for identifying agents that decrease pathogenicity of all retroviruses by measuring Rab11A activity. Claims 41, 48, 60 and 61 have been canceled. Amended claim 40 is directed to a method of identifying an agent that decreases viral infection. Applicants believe these amendments render the pending 35 U.S.C. §112, first paragraph, written description rejection moot. Moreover, as stated above, the specification provides written support for numerous exemplary methods for identifying agents that decrease viral infection by monitoring Rab11A activity or expression, including page 39, line 16 – page 41, line 28, Example 13 and Example 14. Therefore, one of ordinary skill in the art would understand how to perform the claimed method (*i.e.*, identify agents that decrease viral infection by detecting the level of viral infection and associating the level of viral infection with Rab11A gene expression or Rab11A activity, wherein a decrease in viral infection associated with a decrease of Rab11A gene expression and/or Rab11A activity indicates that the test agent is an agent that decreases viral infection) and would recognize that Applicants were in possession of the claimed invention at the time of filing. Therefore, the pending claims are sufficiently

described by the specification. Applicants believe that the amended claims comply with the written description requirement.

For all of these reasons, Applicants request that the pending 35 U.S.C. §112, first paragraph, rejections be withdrawn.

***Newly Added Claims 62-65***

Newly added claims 62 and 63 depend from claim 40. As such, claims 62 and 63 satisfy the criteria for patentability for at least the same reasons presented above for such claims. Claims 64 and 65 are also believed to be in condition for allowance for all of the reasons set forth above.

## Conclusion

Based on the foregoing amendments and arguments, the claims are in condition for allowance and notification to this effect is requested. The Examiner is formally requested to contact the undersigned prior to issuance of the next Office action, in order to arrange a telephonic interview. It is believed that a brief discussion of the merits of the present application may expedite prosecution.

Respectfully submitted,

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